

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,)	
)	
)	
Plaintiff,)	
)	Civil Action No.: 06-222 (JJF)
v.)	
)	
IMPAX LABORATORIES, INC.,)	
)	
Defendant.)	
_____)	

**STIPULATED PROTECTIVE ORDER REGARDING THE PRODUCTION OF
DOCUMENTS BY ALZA CORPORATION IN RESPONSE TO SUBPOENA**

WHEREAS, Defendant Impax Pharmaceuticals served on third party Alza Corporation (“Alza”) a subpoena issued by the District Court for the Northern District of California, (“the Subpoena”), requesting the production of certain documents and information for use in the above-styled proceeding (the “Proceeding”), many of which contain trade secrets, or other confidential and proprietary, scientific, technical, financial, strategic, business planning, business arrangement, competitive, research, development, or other kinds of commercially sensitive information within the meaning of Federal Rule of Civil Procedure 26(c)(7);

WHEREAS, Alza and the parties, through their respective counsel, have agreed that a Stipulated Protective Order preserving the confidentiality of certain documents and information produced in response to the Subpoena should be entered by the United States District Court for the District of Delaware; and

WHEREAS, the parties have established good cause for entry of this Stipulated Protective Order;

IT IS HEREBY STIPULATED AND AGREED, SUBJECT TO THE APPROVAL AND ORDER OF THE COURT THAT:

1. Alza may designate as "Highly Confidential" all or any part of any discovery and other materials produced in response to the Subpoena that contain sensitive financial, patent, trademark, copyright, trade secret, marketing, customer, research, manufacture, regulatory, commercial, business, strategic, or product development information, or any other confidential technical or non-technical information or know-how of such a nature as to be protectable under Federal Rule of Civil Procedure 26(c)(7).

2. Material designated by Alza as Highly Confidential information, including all information derived therefrom, and all copies, summaries, abstracts, excerpts, indices, and descriptions of such material shall be held in confidence by the receiving party, shall be used only by persons permitted access to it under this Protective Order, and shall not be used for any purpose other than in connection with this litigation or appeal of this Proceeding. Material designated by Alza as Highly Confidential information shall not be used for any research, development, manufacture, patent filing or prosecution, financial purpose, commercial purpose, marketing purpose, business purpose, regulatory purpose, Citizen's Petitions, lawsuits against the FDA, or any other litigation, regulatory or administrative proceeding, mediation or arbitration.

Designation Procedure

3. Designation by Alza of a document or thing as Highly Confidential information shall be made by stamping it with the legend "HIGHLY CONFIDENTIAL" or "HIGHLY CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER" as reasonably appropriate when it is produced. As used in this Order, these two legends are interchangeable. Anything that cannot be so marked on its face shall be marked by placing the appropriate legend on a container or

package in which the thing is produced or on a tag attached thereto. Each page of each document and each thing produced in response to the Subpoena shall bear an identifying number.

Documents and things produced by Alza without a legend designating the material Highly Confidential shall not be subject to this Protective Order unless otherwise agreed by the parties and Alza or ordered by the Court, or otherwise designated Highly Confidential in accordance with the provisions of paragraph 10 of this Protective Order.

Access to Confidential Information

4. Documents and materials marked by Alza as "Highly Confidential" information may be disclosed only to the following Qualified Persons:

a. attorneys from the following firms who have or are working on the present litigation (and the paralegals, assistants and employees of the respective law firms of such outside counsel to the extent such person's duties and responsibilities require access to such material):

Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.;

Morris, Nichols, Arsht & Tunnell, L.L.P.;

Heller Ehrman, L.L.P.; and

Morris James, L.L.P.; and

the following in-house counsel at Wyeth (and the paralegals and assistants of such counsel to the extent such person's duties and responsibilities require access to such material):

Susan Lee, Esq. and

Lawrence Alaburda, Esq.

The addition or substitution of any attorneys as Qualified Persons beyond those identified in this paragraph may be made only upon written agreement of Alza. Documents produced by Alza in response to the Impax Subpoena and marked as "Highly Confidential" will not be used for any purpose other than in connection with the Wyeth v. Impax Proceeding;

b. independent litigation support service personnel, litigation consultants, outside exhibit preparation companies, or litigation study groups retained by a party for litigation support with whom such outside counsel work in connection with this Proceeding to the extent such persons have a written agreement with outside counsel to maintain the confidentiality of their work, and provided that such personnel are regularly engaged in the provision of such services, and are not engaged in the research, development, manufacture, marketing, or sale of pharmaceutical products, provided that no person identified in this subparagraph have any involvement in The Texas Litigation or The Reexamination from receipt of any documents produced by Alza in response to the Impax Subpoena and marked "Highly Confidential" until the date for Alza's document production under P.R. 3-2 of the E. D. Texas rules in The Texas Litigation;

c. any independent outside consultant or expert to the parties that is assisting outside counsel, is not a current employee of any of the parties in the litigation, and has been otherwise approved to see Confidential information in this litigation, provided that no person identified in this subparagraph shall have any involvement in The Texas Litigation or The Reexamination from receipt of any documents produced by Alza in response to the Impax Subpoena and marked "Highly Confidential" until the date for Alza's document production under P.R. 3-2 of the E. D. Texas rules in The Texas Litigation;

d. the Court and any members of its staff to whom it is necessary to disclose Highly Confidential information for the purpose of assisting the Court in this Proceeding and stenographic employees, court reporters and typists for the sole purpose of recording, or transcribing testimony, documents or information relating to this Proceeding;

e. interpreters and translators for the sole purpose of recording, transcribing or translating testimony or documents relating to this Proceeding to the extent such persons have a written agreement with outside counsel to maintain the confidentiality of their work, and provided that such personnel are regularly engaged in the provision of such services, and are not engaged in the research, development, manufacture, marketing, or sale of pharmaceutical products, provided that no person identified in this subparagraph shall have any involvement in The Texas Litigation or The Reexamination from receipt of any documents produced by Alza in response to the Impax Subpoena and marked "Highly Confidential" until the date for Alza's document production under P.R. 3-2 of the E. D. Texas rules in The Texas Litigation;

f. any person who prepared a particular document or thing, or who is listed on the document as a sender or recipient of the document, but the disclosure shall be limited to the specific Highly Confidential information disclosed in the particular document or thing.

As a condition precedent to disclosure of Highly Confidential information to independent outside consultants or experts referred to in subparagraph (c) above, counsel who retained the expert or consultant shall forward a copy of a written agreement to be bound by the terms of this Order and a copy of the expert's complete most recent curriculum vitae, including a list of publications, to counsel for Alza at least ten (10) court days prior to disclosure to such person. If Alza objects to the proposed disclosure within ten (10) court days after receipt of the

notice, the disclosure may not be made without prior approval by the Court. Any objection shall state with particularity the basis for the objection.

5. Nothing contained in this Order shall preclude any party or Alza from using its own confidential information in any manner it sees fit, without prior consent of any party or the Court.

Further, nothing contained in this Order shall preclude disclosure to current or former Wyeth employees of documents to which Wyeth has already had access, including but not limited to the following categories of documents produced by Alza:

- a. correspondence between Wyeth and Alza;
- b. documents where one or more Wyeth employees are listed on the document as an author, sender, or recipient of the document; and
- c. documents which originated from Wyeth's files.

Notwithstanding the designation of documents or information as Highly Confidential, such documents or information may be used for any purpose and be freely disclosed to anyone if the documents or information were also obtained independent of discovery produced in response to the Subpoena and for which no other obligation of confidentiality applies. Accordingly, nothing in this Order shall prevent any person, including a Qualified Person, from using for any purpose or freely disclosing to anyone any document or information that is designated Highly Confidential if such document or information:

- a. was lawfully in his or her possession prior to receipt under the provisions of this Order;
- b. was or becomes available to the public through no fault of a receiving party; or

c. was or is obtained from a source not under an obligation of secrecy to the producing party.

Inadvertent Production/Use of Confidential Information and Changes in Designation

6. Inadvertent production by Alza of any document or information without a designation of Highly Confidential will not be deemed to waive a later claim as to its confidential nature or stop Alza from designating said document or information as Highly Confidential.

7. Alza may change a designation to Highly Confidential (or withdraw a designation) regarding any material that it has produced. Such change in designation (or withdrawal) shall be accomplished by notifying counsel for each party in writing of such change in designation (or withdrawal). Upon receipt of any such written change in designation counsel of record shall: (i) not make any further disclosure or communication of such newly designated material except as provided for in this Order; (ii) take reasonable steps to notify any persons known to have possession of any material with the original designation of the effect of such a change in designation under this Order; and (iii) promptly retrieve all copies and transcriptions of such originally designated material from any persons known to have possession of any such originally designated material who are not Qualified Persons under paragraph 3 above in light of the change of designation to the extent practicable. Properly marked documents shall be promptly provided by Alza of any such newly designated material.

8. If Highly Confidential information is disclosed to any person other than in the manner authorized by this Order, the party responsible for the disclosure shall within five (5) court days of learning of such disclosure inform Alza of all pertinent facts relating to such disclosure and shall obtain the prompt return of any such Highly Confidential information.

Inadvertent Production/Use of Privileged Information

9. If information subject to a claim of attorney-client privilege, attorney work product immunity or other legal privilege protecting information from discovery is inadvertently produced by Alza in any way, such production shall not prejudice or otherwise constitute a waiver (subject matter or otherwise) of, or estoppel as to, any claim of privilege, work product immunity, or other ground for withholding production to which the producing party or other person otherwise would be entitled. If a written claim of inadvertent production is made by a Alza pursuant to this paragraph the parties shall:

- (a) not make any further copies or other reproductions or transcriptions of the inadvertently disclosed information or document; and
- (b) destroy or return to Alza every original and every copy, reproduction, or transcription of all such inadvertently produced information or documents.

**Alza's Disclosure of Information of Third-Parties
Pursuant to the Subpoena**

10. Any documents Alza produces in response to the Subpoena that are subject to confidentiality agreements between Alza and Plaintiff Wyeth shall be designated as Highly Confidential and may be produced to Wyeth and Impax pursuant to this Order without objection by Wyeth.

11. Any party that is served with a subpoena or other notice compelling the production of any Highly Confidential materials produced by Alza is obligated to give prompt telephonic and written notice (by hand delivery, courier or facsimile transmission) to Alza of such subpoena or other notice. In any event, such notice shall be given within five (5) court days of service of the subpoena or other notice. If Alza takes steps to oppose the subpoena, then the party served with the subpoena shall not disclose the pertinent information until the Court has resolved the issue.

Absent Court order, production or disclosure shall not be made before notice is given to Alza and Alza has had at least ten (10) court days to react after receiving such notice. Upon receiving such notice, Alza shall bear the burden to oppose, if it deems appropriate, the subpoena on grounds of confidentiality.

Use of Highly Confidential Information in Filings and in Open Court

12. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other proceeding of any document, testimony, or other evidence.

13. The Clerk of the Court is directed to maintain under seal any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court that has been designated, in whole or in part, as containing or revealing Highly Confidential information.

14. In the event that a party wishes to use any Highly Confidential information in any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court, such paper shall be enclosed in a sealed envelope or other appropriate container. The sealed envelope or other appropriate container shall:

- (a) show the caption of this action;
- (b) identify its contents; and
- (c) include the following legend:

HIGHLY CONFIDENTIAL INFORMATION PURSUANT TO STIPULATED PROTECTIVE ORDER: This envelope [or container] is sealed pursuant to court order and contains confidential information. The contents of this envelope must not be shown to any person except as authorized by the Protective Order Regarding the Production of Documents by Alza Corporation in Response to Subpoena in this action.

15. To the extent that a party (or a witness called by a party) contemplates using Highly Confidential information, which was produced by Alza, at trial or a hearing in open court and to

the extent that a party moves for or agrees to the unsealing of any previously sealed pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court, the party shall have the obligation to provide notice in writing to Alza of its intent. Alza shall have at least ten (10) court days after receiving such notice to respond to that notice before any of its Highly Confidential may be unsealed or used by any party at trial or a hearing in open court. In the event that Alza objects to the use or unsealing of the information, the party wanting to use or unseal the information shall bear the burden of establishing the need for such use and the adequacy of the protection of such information. In lieu of moving to use the Highly Confidential information in open court, the party wishing to use the information may request (with prior notice to Alza) that the Court close those portions of the proceedings in which the Highly Confidential information is to be used to all persons except Court personnel and persons authorized to receive Highly Confidential information produced by Alza under this Order.

Disposition of Confidential Materials upon Conclusion of Proceeding

16. Upon the conclusion of this Proceeding, including any appeals related thereto, at the option of Alza, all information and documents designated by Alza as Highly Confidential and any and all copies and transcriptions thereof, shall either be destroyed or returned within ninety (90) calendar days to counsel for Alza, provided, however, that outside counsel may retain all documents and things that contain or reflect their attorney work product – e.g., notes, memoranda, drafts of pleadings, deposition summaries, document review summaries, documents reviewed in preparation for depositions, hearings, or trial whether introduced or not – all correspondence, all pleadings, all deposition transcripts, all expert reports, all deposition, hearing and trial exhibits, and all court-filed documents even though they contain Highly Confidential information, but such retained work product and documents shall remain subject to the terms of

this Order. Accordingly, upon final termination of this action, no one other than outside counsel shall retain any information designated Highly Confidential by Alza. Any person or entity having received recordings, notes, memoranda, summaries or other written materials, and all copies thereof, relating to or containing Alza Highly Confidential information shall deliver to Alza a declaration confirming that all such Highly Confidential information and any copies thereof, any and all records, notes, memoranda, summaries or other written material regarding the Highly Confidential information (except for attorney work product and documents permitted to be retained by outside counsel as stated above), have either been destroyed or delivered to counsel for Alza in accordance with the terms of this Order.

Miscellaneous Provisions

17. This Order shall be binding upon the parties to this Proceeding and Alza, including their successor(s) and assigns, and their respective attorneys, agents, representatives, officers and employees.

18. This Order shall apply to all information and material produced by Alza in response to the Subpoena, including all information and material produced prior to the execution of this Order by the Court.

19. The parties and Alza acknowledge and agree that if any party hereto breaches, or threatens to commit a breach of any of the provisions of this Order, Alza shall have the right to seek appropriate remedies from the Court, which remedies shall be in addition to and not in lieu of, any other remedies available to Alza under law or in equity, to have the Order specifically enforced (without posting any bond), including, without limitation, the right to an entry against the breaching party of restraining orders and injunctions (preliminary and permanent) against breaches, threatened or actual, it being agreed and acknowledged that, in the event of any such

breach or threatened breach, the breaching party is not entitled to a presumption that money damages or legal remedies are sufficient or adequate to remedy such a breach.

20. By written agreement of the parties and Alza, or upon motion (with notice to Alza) and order of the Court, the terms of this Order may be amended or modified except as provided in paragraph 4 hereof.

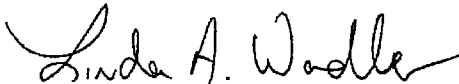
21. This Order shall survive termination of this Proceeding, including any final judgment, appeal, or settlement to the extent the Highly Confidential information is not or does not become known to the public.

22. Nothing in this Order shall prejudice the right of Alza to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality.

23. In the event that a new party is added, substituted, or otherwise brought into this Proceeding, this protective order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this protective order.

24. The entry of this Order does not prevent any party from seeking a further order of this Court pursuant to Federal Rule of Civil Procedure 26(c).

Dated: _____



Jack B. Blumenfeld (I.D. No. 1014)
Karen Jacobs Loudon (I.D. No. 2881)
Morris, Nichols, Arsht & Tunnell
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
Telephone: (302) 658-9200
Facsimile: (302) 658-3989
jblumenfeld@mnat.com
kloudon@mnat.com

Basil J. Lewris (*pro hac vice*)
Linda A. Wadler (*pro hac vice*)
Finnegan, Henderson, Farabow,
Garrett & Dunner L.L.P.
901 New York Avenue, N.W.
Washington, DC 20001
Telephone: (202) 408-4000
Facsimile: (202) 408-4400

Attorneys for Plaintiff
WYETH



Harry J. Roper
Steven R. Trybus
Jenner & Block LLP
330 North Wabash Avenue
Chicago, IL 60611-7603
Telephone: (312) 222-9350
Attorneys for Alza Corporation

The Honorable Joseph J. Farnan, Jr.
UNITED STATES DISTRICT JUDGE



Mary B. Matterer (I.D. No. 2696)
Morris James Hitchens & Williams LLP
222 Delaware Ave., 10th Floor
Wilmington, DE 19801
Telephone: (302) 888-6800
Facsimile: (302) 571-1750
mmatterer@morrisjames.com

M. Patricia Thayer (*pro hac vice*)
John M. Benassi (*pro hac vice*)
Jessica R. Wolff (*pro hac vice*)
Daniel N. Kassabian (*pro hac vice*)
Samuel F. Ernst (*pro hac vice*)
Heller Ehrman LLP
4350 La Jolla Village Drive, 7th Floor
San Diego, CA 92101
Telephone: (858) 450-8400
Facsimile: (858) 450-8499

Attorneys for Defendant
IMPAX LABORATORIES, INC.